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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,252	02/15/2006	Florence Guimberteau		8812

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,252	GUIMBERTEAU ET AL.	
	Examiner	Art Unit	
	NABILA EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/2009 has been entered.

Double Patenting

In view of abandoning application 10/522234, the rejection of claims 16, 17 and 19-31 on the ground of nonstatutory obviousness-type double patenting is herein withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 19-26 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 as amended recites that "the coating film is between at least about 3% and about 7%". The instant specification does not support this recitation. While the specification recites at least 3%, preferably at

least 5% and most preferred a range of 3 and 40% dry weight/dry weight. There is no support for the recitation of the range recited of at least 3%, to 7%. In accordance with MPEP 714.02 applicants should specifically point out support for the generic concept of claim 1 using the range "the coating film between at least about 3% and about 7%"

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17, and 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "wherein the coating film is between at least about 3% and about 7% dry weight/dry weight of the microcapsule mass", it is not clear if "at least" is only used for the percentage of 3% or it includes also the percentage of 7%. For the purpose of examining the claim, it will be interpreted as written "at least about 3%" and "about 7%".

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In view of amending the claims, the rejection of claims 16, 17, 19-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta US 5084278 (Mehta) is herein withdrawn. **Applicant is still required to show support for the amendments to the claims on which withdrawing the rejection is based.**

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 16-17, and 19-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta US 5084278, in view of Mulye US 6946146 (Mulye).

Mehta teaches microcapsule with a core wherein the core comprises an active agent and a diluent (corresponds to the solubilizing agent in the instant claims). The core is surrounded by a coating which comprises a film-forming polymer (abstract). preferred coating composition is a mixture comprised of at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating (col. 4, lines 24+). A preferred high temperature film forming polymer can be ethyl cellulose (col. 5, line 21). The low temperature film forming polymer can be any of a group of plasticizers including glyceryl triacetate polyvinyl pyrrolidone (col. 5, lines 41+). The microcapsules are 0.25-1 mm in diameter (col. 2, lines 21-22). The diluent added to the core material may be hydroxypropyl or hydroxypropyl methyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone, and ethylcellulose among others (col. 8, lines 10+). Note that since the same polymers are used with the active agent in the core, it should be capable of increasing the solubility of the at least one active principle by more than 50% as required by instant claim 1. Mehta also discloses the use of lubricants such as magnesium stearate (col. 8, line 14). The microcapsules can be prepared to release the active agent in the intestine (col. 6, lines 33-34), the disclosure is understood as the

coating polymer is not soluble in the stomach as required in the instant claims. The drugs that can be comprised in the core are antibiotics, and ibuprofen among others (col. 7, lines 48+). It is noted that since Mehta teaches the same microcapsule ingredients in the same structure and amounts, and since the mass fraction is calculated as:

Mass fraction (w_A) is the ratio of the mass of substance A to the total mass of a mixture.

It is expected that Mehta's ingredient mass fraction would have the same value recited in the claims. Regarding the release profile recited in claim 16, absent of evidence on the contrary, the burden is shifted to applicant to show that the microcapsules taught by Mehta would not exhibit the claimed properties. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant application, Mehta teaches the use of the same coating composition comprising the same ingredients, and in the same concentrations.

Regarding the new amendments to the claims which recite that "the coating film is between at least about 3% and about 7% dry weight/dry weight of the microcapsule mass". The word "about" demonstrates a relative meaning or amount, thus if Mehta discloses a preferred coating composition is a mixture comprised of at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming

polymer based on the total weight of polymer in the microcapsule coating. Thus the amount may overlap and the rejection under 35 U.S.C. §103 remains proper. Further, new claim 32 recites that the mass fraction by dry weight of P1 relative to the total mass of the coating is between 50 and 80%, the mass fraction by dry weight of P2/P1+P2 is between 15 and 55% relative to the total mass of the coating; the mass fraction by dry weight of PL/P1+PL is between 5 and 25% relative to the total mass of the coating; and wherein the mass fraction by dry weight of TA is between 4 and 15%. Since Mehta recites amount of the coating that overlaps the new range recited in the instant claims, then values of the mass fraction required by the claim are also overlapping and obvious.

Mehta does not explicitly teach the amount of the claimed lubricant surfactant.

Mulye teaches coating for sustained release pharmaceutical composition. The coating composition of the invention may be used to coat various cores or substrates containing the active ingredient such as tablets, spheroids (or beads), microspheres. The dosage form contains cores which contain the medicament or therapeutically active agent which is administered to a mammal. The coating layer may include a lubricant. Examples of suitable lubricants include calcium stearate, colloidal silicon dioxide, magnesium stearate, aluminum stearate, or a mixture of any two or more of the forgoing, and the like. If present, the lubricant is present in amounts ranging from about 0.01% to about 10% by dry weight of the coating (col. 8, lines 38+).

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microcapsule of Mehta using a lubricant in an amount around the percentage disclosed by Mulye in the coating because Mehta

teaches microcapsules having sustained/modified release profiles. The expected results would be an orally administered microcapsule having cores containing an active agent and a solubilizing compound and having a coating which comprises two kinds of polymers, one is a film forming and not soluble in the stomach and the other is water soluble, a plasticizer and a lubricant.

Response to Arguments

1. Applicant's arguments filed 2/19/2009 have been fully considered but they are not persuasive. Applicant argues that:

REJECTIONS UNDER 35 U.S.C. § 102

- The arguments render moot in view of withdrawing the rejection.

REJECTIONS UNDER 35 U.S.C. § 103

- The instant claim requires the coating film be between about 3% and about 7% dry weight/dry weight of the microcapsule mass. Mehta, however, teaches that the coating is 20 - 40% by weight of the microcapsules. This teaching of Mehta is expected for the use that Mehta teaches: blocking taste. Mehta is directed to compositions that mask taste so the drug, when chewed, does not produce a bitter taste.

To respond: Applicant alleges that the instant subject matter includes a coating film be between about 3% and about 7% dry weight/dry weight of the microcapsule mass as the claims are newly amended. However, the instant specification teaches at least 3% and at least 5% dry weight/dry weight. Even if the specification contains support for the recitation, it is noted that using the word "about" in the instant percentage of between

about 3% and 7% and since Mehta uses the word "about" in the disclosed amount of 10%, then it is a very close and obviously overlapping percentages.

- There is no suggestion or motivation to modify the reference or to combine reference teachings. Mehta teaches coatings to mask taste, whereas Mulye teaches latex dispersion coats to control release of a drug. Mehta teaches microcapsules of 0.25 – 1 mm in diameter, and Mulye doesn't teach a microcapsule of any diameter.

To respond: Both references are concerned with dissolution like the instant application. For example, see the dissolution studies in Mehta in Example 2. Note that for the disclosure being concerned with masking the taste does not contradict with having other concerns and/or achievements such as improving dissolution. Further, in Mulye, see figures 1 and 2 and 3 that shows the dissolution rates of a drug with or without coating.

- Examiner has not shown a teaching or suggestion to make the claimed invention, with any reasonable expectation of success. These elements must be found in the prior art. In re Vaeck, 947 F.2d 488; Hodosh, 786 F.2d 1143 n.5. The Examiner has not shown where in the art the addition of a lubricant, which is known to alter the chemical properties, to Mehta would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

To respond: Mehta disclosed a lubricant that is recited in instant claim 28 which is magnesium stearate. However, the reference did not teach the amount used. Mulye is relied upon only for the amount of the lubricant used not for teaching a lubricant. Thus, Mehta does need to be modified and Mulye is relied upon to show that the right amount

used for improving the dissolution was known in the art at the time the claimed invention was made.

- Mehta is so vague and obtuse that it is unclear which compounds are "high" or "low" temperature film forming polymers and how they are to be combined and/or used. In Mehta a compound can be both a high temperature and low temperature film-forming polymer. One with skill in the art would not have a reasonable expectation of success, because they would not know how to combine the vague and confusing Mehta with Mulye.

To respond: Mehta teaches microcapsule with a core wherein the core comprises an active agent and a diluent (corresponds to the solubilizing agent in the instant claims). The core is surrounded by a coating which comprises a film-forming polymer. The active agent is mixed with the same polymers such as polyvinyl alcohol, polyvinyl pyrrolidone and the coating is made from the same polymers such as ethylcellulose. Regarding Applicant allegation that Mehta is vague and the disclosure is confusing, it is noted that Mehta is a patent constituting a prior art for the instant claims and is not under current prosecution.

- Mehta and Mulye are nonanalogous arts because their coatings have a different structure composition to serve different purposes. Their problems are in no way same or similar.

To respond: In response to applicant's argument that Mulye and Mehta are nonanalogous arts, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Mulye is concerned with controlling dissolution of drugs as seen for example in figures 1-3. The reference in specific is concerned with dissolution of drugs having low solubility in water such as Glipizide (see Fig. 2). Regarding Mehta, the reference literally teaches that in each of the disclosed embodiments, excipients and other additives may be added to **aid solubility** and/or compressibility (col. 1, lines 18+) and the embodiments include coating to control solubility and release. The two references are having same endeavor as the instant claims.

- Applicant argues that constituents, such as polymers, that belong to the same chemical group can have very different products and piece. These properties are well known and a matter of common knowledge to one of skill in the art. For example, all of the Mulye applications below use starch (CAS Registry No. 9005-25-8) for very different reasons. Applicant gives detailed examples of starch, its different types and properties to explain his position.

To respond: it is respectfully noted that neither the instant claims comprise starch nor does the office action; consequently, Applicant's position is not clear. It is expected that the Applicant should be specific to make responding possible. Since Applicant does not argue a specific polymer that is cited in the office action then comparison of properties cannot be made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618